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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/626,366	07/24/2000	Cathy Ilyse Hess	D4857-00006	7385

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DUANE MORRIS, LLP
ATTN: WILLIAM H. MURRAY
ONE LIBERTY PLACE
1650 MARKET STREET
PHILADELPHIA, PA 19103-7396

EXAMINER
FRENEL, VANEL

ART UNIT	PAPER NUMBER
3626	

DATE MAILED: 05/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/626,366	Applicant(s) HESS, CATHY ILYSE
	Examiner Vanel Frenel	Art Unit 3626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Notice to Application

1. This communication is in response to the amendment filed 02/24/03. Claims 1-3, 5, 9,10 and 15 have been amended. Claims 1-16 are pending.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dang (6,370,511) in view of Hennessy et al (6,277,071).

(A) As per claim 1, Dang discloses a computer-implemented method for assessing deviations from a preselected medical treatment that has been indicated by appropriate diagnosis from a clinician, comprising the steps of:

(A) gathering patient care data and diagnosing a malady (Col.9, lines 21-61);

(B) storing said patient care data and said diagnosis of said malady in a data storage means as a data record (Col.12, lines 40-67);

(C) identifying an appropriate clinical pathway to follow in treating said diagnosed malady from a plurality of clinical pathways stored in said data storage means (Col.12, lines 27-67 to Col.13, line 27);

(D) implementing said identified clinical pathway and recording each clinical action taken by a clinician as data record in said data storage means (Col.12, lines 27-67).

Dang does not explicitly disclose monitoring and comparing said recorded clinical actions taken by said clinician to said identified clinical pathway so as to identify one or more to variations from said identified clinical pathway; and issuing an alert notice to said clinician at the time of performance of said identified clinical action identified as a variance from said identified appropriate clinical pathway.

However, these features are known in the art, as evidenced by Hennessy. In particular, Hennessy suggests monitoring and comparing said recorded clinical actions taken by said clinician to said identified clinical pathway so as to identify one or more to variations from said identified clinical pathway; and issuing an alert notice to said clinician at the time of performance of said identified clinical action identified as a variance from said identified appropriate clinical pathway (See Hennessy Col.5, lines 30-67 to Col.6, line 51; Col.9, lines 64-67 to Col.10, line 56).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the features of Hennessy within the system of Dang with the motivation of providing a processor which separates the patient entries designated by the user according to a test threshold stored in said guideline. The test thresholds represent known parameters associated with the chronic disease, such as blood glucose, lipids, liver enzyme and microalbumin for the disease of diabetes. If the test threshold value derived from the guideline is exceeded, an alert sequence is activated, in which the patient is categorized

as a high risk patient, the physician is notified, the patient is notified, the health care provider is notified, and the patient's treatment is altered to treat the high risk patient (See Hennessy Col.4, lines 26-37).

(B) As per claim 2, Hennessy discloses a method according wherein said gathering of said patient care data includes applying a risk assessment tool comprising a rating scale to objectively characterize the subjective condition of said patient's skin and wound (See Hennessy Fig.20; Col.10, lines 29-60).

The motivation for combining the respective teachings of Dang and Hennessy are as discussed above in the rejection of claim 1, and incorporated herein.

(C) As per claim 3, Hennessy discloses a method according wherein said rating scale identifies factors most closely associated with the formation of a selected malady (Col.2, lines 36-67 to Col.3, line 8).

The motivation for combining the respective teachings of Dang and Hennessy are as discussed above in the rejection of claim 1, and incorporated herein.

(D) As per claim 4, Hennessy discloses a method wherein said factors are associated with parameters that are identified and assessed by said clinician, and a rating number assigned to each of said parameters that corresponds to said clinician's objective assessment of a wound/skin condition (See Hennessy Fig.20; Col.10, lines 1-60).

The motivation for combining the respective teachings of Dang and Hennessy are as discussed above in the rejection of claim 1, and incorporated herein.

(E) As per claim 5, Hennessy discloses a method wherein a finite numerical score is selected from a preselected range and assigned to each of said parameters (Col. 9, lines 29-63).

The motivation for combining the respective teachings of Dang and Hennessy are as discussed above in the rejection of claim 1, and incorporated herein.

(F) As per claim 6, Hennessy discloses a method wherein a numerical score at or above a preselected value is indicative of a high risk for development of said malady (Col.9, lines 64-67 to Col.10, line 23).

The motivation for combining the respective teachings of Dang and Hennessy are as discussed above in the rejection of claim 1, and incorporated herein.

(G) As per claim 7, Hennessy discloses a method wherein said parameters, along with their assigned scores, are stored at a known, searchable, and retrievable location in said data storage means (Col.9, lines 29-63).

The motivation for combining the respective teachings of Dang and Hennessy are as discussed above in the rejection of claim 1, and incorporated herein.

(H) As per claim 8, Hennessy discloses a method wherein said monitoring includes reviewing each of said parameters, and identifying a most likely course of intervention to be followed by said clinician (Col.11, lines 1-45).

The motivation for combining the respective teachings of Dang and Hennessy are as discussed above in the rejection of claim 1, and incorporated herein.

(I) As per claim 9, Dang discloses a computer-implemented method for assessing deviations from a preselected medical treatment that has been indicated by appropriate diagnosis from a clinician, comprising the steps of:

(A) gathering patient care data and diagnosing a malady (Col.9, lines 21-61);

(B) storing said patient care data and said diagnosis of said malady in a data storage means of a general purpose computer as a data record (Col.12, lines 40-67);

(C) identifying an appropriate clinical pathway to follow in treating said diagnosed malady from a plurality of clinical pathways stored in said data storage means (Col.12, lines 27-67 to Col.13, line 27);

(D) implementing said identified clinical pathway and recording each clinical action taken by a clinician as a data record in said data storage means (Col.12, lines 27-67).

Dang does not explicitly disclose monitoring and comparing said recorded clinical actions taken by said clinician to said identified clinical pathway at the time of performance of said clinical action identified as a variance.

However, these features are known in the art, as evidenced by Hennessy. In particular, Hennessy suggests monitoring and comparing said recorded clinical actions taken by

said clinician to said identified clinical pathway at the time of performance of said clinical action identified as a variance (See Hennessy Col.5, lines 30-67 to Col.6, line 51; Col.9, lines 64-67 to Col.10, line 56).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the features of Hennessy within the system of Dang with the motivation of providing a processor which separates the patient entries designated by the user according to a test threshold stored in said guideline. The test thresholds represent known parameters associated with the chronic disease, such as blood glucose, lipids, liver enzyme and microalbumin for the disease of diabetes. If the test threshold value derived from the guideline is exceeded, an alert sequence is activated, in which the patient is categorized as a high risk patient, the physician is notified, the patient is notified, the health care provider is notified, and the patient's treatment is altered to treat the high risk patient (See Hennessy Col.4, lines 26-37).

(J) As per claim 10, Hennessy discloses a method wherein said gathering of said patient care data includes observing and recording a patient's vital signs (Col.7, lines 26-51).

The motivation for combining the respective teachings of Dang and Hennessy are as discussed above in the rejection of claim 9, and incorporated herein.

(K) As per claim 11, Hennessy discloses a method wherein said recorded vital signs are each compared to a preselected value for said vital sign and monitored for deviations that are indicative of a high risk for development of a skin malady (See Hennessy Fig.20; Col.10, lines 1-60).

The motivation for combining the respective teachings of Dang and Hennessy are as discussed above in the rejection of claim 9, and incorporated herein.

(L) As per claim 12, Hennessy discloses a method wherein said implementing said identified clinical pathway and recording clinical actions taken by said clinician includes implementing a skin and wound care regimen (Col.2, lines 1-35; Col.6, lines 30-67).

The motivation for combining the respective teachings of Dang and Hennessy are as discussed above in the rejection of claim 9, and incorporated herein.

(M) As per claim 13, Hennessy discloses a method wherein said skin and wound care regimen are monitored for deviations that are indicative of a high risk for deterioration of said skin and wound (Col.6, lines 12-67).

The motivation for combining the respective teachings of Dang and Hennessy are as discussed above in the rejection of claim 9, and incorporated herein.

(N) As per claim 14, Hennessy discloses a method wherein said regimen comprises selection and application of dressings to a wound (See Hennessy Fig.20; Col.6, lines 30- 67).

The motivation for combining the respective teachings of Dang and Hennessy are as discussed above in the rejection of claim 9, and incorporated herein.

(O) Claim 15 differs from claims 1 and 9 by reciting a method for assessing deviations from a preselected medical treatment that has been indicated by appropriate diagnosis from a clinician, comprising the steps of:

(A) gathering patient care data according to a predetermined regimen for diagnosing a malady of the skin;

(B) storing said patient care data in a data storage means of a general purpose computer.

As per this limitation, it is noted that Dang discloses (C) identifying an appropriate clinical pathway from a plurality of pathways for treating said diagnosed malady (Col.12, lines 27-67 to Col.13, line 27);

(D) implementing said identified clinical pathway via clinical actions taken by a clinician (Col.12, lines 27-67) and Hennessy discloses monitoring said clinical actions taken by said clinician to determine variations from said identified clinical pathway; and alerting said clinician of a variance from said identified clinical pathway (See Hennessy Col.5, lines 30-67 to Col.6, line 51; Col.9, lines 64-67 to Col.10, line 56).

Thus, it is readily apparent that these prior art systems utilize a predetermined regimen to perform their specified function.

The remainder of claim 16 is rejected for the same reason given above for claims 1 and 9, and incorporated herein.

(P) As per claim 16, Hennessy discloses a method wherein said regimen comprises answering a questionnaire that quantifies a patient's satisfaction with his/her health status (See Hennessy Col.2, lines 8-35).

The motivation for combining the respective teachings of Dang and Hennessy are as discussed above in the rejection of claim 9, and incorporated herein.

Response to Arguments

4. Applicant's arguments filed 2/24/03 regarding claims 1-16 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 2/24/03.

(A) At page 10 of the 2/24/03 response, Applicant apparently argues that a prima facie of obviousness has not been established.

In response, the Examiner respectfully submits that obviousness is determined on the basis of the evidence as a whole and the relative persuasiveness of the arguments. See In re Oetiker, 997 F.2d 1443,1445, 24 USPQ2d 1443,1444 (Fed. Cir. 1992); In re Hedges, 783 F.2D 1038, 1039, 228 USPQ 685, 686 (Fed. Cir. 1992); In re Piasecki, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984); and In re Rinehart, 531 F.2d 1048, 1052, 189 USPQ 143,147 (CCPA 1976). Using this standard, the Examiner respectfully submits that he has at least satisfied the burden of presenting a prima facie case of obviousness, since he has presented evidence of corresponding claim elements in the prior art and has expressly articulated the combinations and the motivations for combinations that fairly suggest Applicant's claimed invention (See paper number 6).

Rather, Applicant does not point to any specific distinction (s) between the features disclosed in the references and the features that are presently claimed. In particular, 37 CFR 1.111 (b) states, "A general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the reference does not comply with the

requirements of this section." Applicant has failed to specifically point out how the language of the claims patentably distinguishes them from the applied references.

(B) At page 11 of the 2/24/03 response, Applicant argues that Dang not disclose monitoring the recorded clinical actions taken by a clinician to determine variations for an identified clinical pathway or, alerting a clinician of a variance from the identified clinical pathway and an alert notice be provided to a clinician at the time of performance of a clinical action that has been identified as a variance from the appropriate clinical pathway. However, Examiner disagrees.

In response to Applicant's arguments, Examiner suggests that Hennessy discloses "a data processing system and method for managing diabetes care where utilizes known medical standards adopted by the American Diabetes Association, among others, to customize a treatment plan, which can interface with the physician, health care plan and patient, and defines a set of criteria which defines a high risk patient and which continually monitors the patient, setting forth alarms which is corresponding to the claimed feature (See Hennessy Col.3, lines 65-67 to Col.4, line 40). Therefore, Applicant's argument is not persuasive.

(C) At page 12, Applicant's argues that Dang fails to suggest or provide the requisite motivation to one of ordinary skill in the art to provide a method for accessing deviations from a preselected medical that has been indicated by an appropriate diagnosis. However, the Examiner disagrees.

In response to Applicant's arguments, Examiner suggests that Hennessy discloses "certain chronic diseases, such as diabetes, have known etiologies and associated risk factors. Guidelines for treatment have been promulgated by, e.g., the American Diabetes Association, the National Commission for Quality Assurance (NCQA) and Diabetes Quality Improvement Project (DQUIP). These guidelines incorporate known complications associated with diabetes such as retinopathy, neuropathy, nephropathy, Pulmonary Vascular Disease (PVD), Cardial Artery Disease (CAD) and cerebral vascular disease. In addition to various tests associated with monitoring the diabetes, such as HbA1c (measuring glycosolated hemoglobin levels), microalbumin (blood protein), lipids (cholesterol), etc., the physician must typically perform routine eye and foot examinations to monitor the progress of the disease" which is corresponding to the claimed feature (See Hennessy Col.1, lines 50-67). Therefore, Applicant's argument is not persuasive.

(D) At page 13, Applicant's argues that Hennessy does not disclose or suggest the issuance of an alert notice for deviations from a standard course of treatment according to an accepted clinical pathway, at the time of performance of the clinical action. However, the Examiner disagrees.

In response to Applicant's arguments, Examiner suggests that Hennessy discloses "the action sequence is also initialized (i.e., alert, quality plan is updated to reflect the need for additional services such as greater frequency in testing blood glucose, information is sent off site 26 to pay provider, employer, health maintenance organization and the like, a letter is generated to the patient, and the appropriate physicians receive an alert concerning the test result /clinical

event) which is corresponding to the claimed feature (See Hennessy Col.10, lines 13-67). Therefore, Applicant argument is not persuasive.

(E) At page 14-15, Applicant's argues neither reference alone, nor their combination evenly vaguely suggests an automatically triggered alerting mechanism that is initiated, in real time, during consultation at bedside, when a treatmentis initiated by a treating physician that deviates from an expected or standard treatment.

In addition, at page 14-15, Applicant states furthermore, the motivation to combine these references is absent from them and since nothing in the prior art references would lead a person of ordinary skill in the art to formulate a method like that described in the application, or defined by claims 1-16, it appears that hindsight knowledge of the present invention is the only motivation to combine these references.

(a) In response to Applicant's arguments, Examiner suggests that Hennessy discloses "a window which is prompted when office visit data is entered into patient record 16. The user may enter the office visit date, practitioner, weight, height, blood pressure, smoking status, blood glucose (SMBG) and daily range, foot exam (PVD, neuropathy, poor skin condition, podiatric referral), quality of life indicators (number of emergency room visits, days of hospitalization, days lost form work) and the patient self assessment. Fig.6 illustrates a window which is prompted for the creation of a patient quality plan 110. The tests to be performed on the patient are selected for enablement, frequency alert (where a value is exceeded), threshold and goal" which is corresponding to the claimed feature (See Hennessy, Col.6, lines 30-67 to Col.7, line 61 specially Col. 7, lines 26-61). Therefore, Applicant argument is not persuasive.

(b) In response to Applicant's arguments it appears that hindsight knowledge of the present invention is the only motivation to combine these references. Examiner respectfully recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the Applicant's disclosure, such a reconstruction is proper. See In re McLaughlin, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Therefore, the combination of references is proper and the rejection is maintained.

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not applied art teaches three step wound treatment method and dressing therefor (4,813,942), system and method for managing patient medical records (5,772,585), medical system and associated method for automatic treatment (5,544,651) and skin patch for use in contact immunotherapy (5,846,559).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vanel Frenel whose telephone number is 703-305-4952. The examiner can normally be reached on 6:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 703-305-9643. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-7687 for regular communications and 703-305-7687 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1113.

V.F
V.F

DINH X. NGUYEN
PRIMARY EXAMINER

May 2, 2003